Medacta International

510(k) Summary

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Date Prepared: April 28, 2014

DEVICE INFORMATION

Trade/Proprietary Name: MySpine Pedicle Screw Placement Guides
Common Name: Pedicle Screw Placement Guide
Classification Name: orthosis, spinal pedicle fixation
21 CFR 888.3070
Class II
Product Code: MNI

Predicate Device: K121115 M.U.S.T pedicle screw system, Medacta International

Product Description

The MySpine Pedicle Screw Placement Guides are patient specific surgical instruments that allow for guided pedicle screw placement of the M.U.S.T pedicle screws (K121115). The M.U.S.T pedicle screws are guided through the patient's anatomically matched MySpine Pedicle Screw Placement Guides in order to provide optimal positioning according to the surgeon's preoperative planning. The MySpine software platform allows the surgeon to complete the preoperative planning in 3D based on the patient's spinal CT scans.

The components of the MySpine Pedicle Screw Placement Guides include a Drill Guide (Polyamide PA 2200), Sleeves for Awls, Probes and Screw Drivers (Polyamide PA 2200), Sleeves for taps and drills (Wrought stainless steel AISI 630, ASTM F 899), and Vertebral Bone Models (Polyamide PA 2200). The MySpine Pedicle Screw Placement Guides are single use, external communicating devices with limited (<24 hours) contact duration and are provided in sterile and non-sterile versions.

Indications for Use

MySpine is intended as a thoracic and lumbar posterior pedicle targeting guide for patients requiring spinal fusion between the levels of T1 to L5.

MySpine Screw Placement Guides are intended to be used as anatomical perforating guides specific for a single patient anatomy to assist intraoperatively in the positioning of Pedicle screws in the vertebral body. MySpine is intended for use with M.U.S.T Pedicle Screw System and its cleared indications for use. Use of the guides involves surgical planning software used pre-operatively to plan the surgical placement of the components on the basis of patient radiological images with identifiable placement anatomical landmarks and surgical equipment components. These components include patient-specific guides fabricated on the basis of the surgical plan to precisely reference the placement of the implant components intra-operatively per the surgical plan.

MySpine Screw Placement Guides are intended for single use only.

Comparison to Predicate Devices

The intended use of the MySpine Pedicle Screw Placement Guides is substantially equivalent to the M.U.S.T pedicle screw system (K121115). The technological characteristics of the MySpine Pedicle Screw Placement Guides do not raise new issues of safety and effectiveness compared to the primary predicate device (K121115). The technological characteristics including design, materials, contact duration, software, manufacturing process, device usage, sterility, packaging, labeling, and shelf-life of the MySpine Pedicle Screw Placement Guides are similar to those of the K093806 MyKnee Cutting Blocks reference device. The safety and effectiveness of the MySpine Pedicle

Screw Placement Guides are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

Performance Testing

No performance standards applicable to this device have been adopted under Section 514 of the Food, Drug and Cosmetic Act. Performance testing of the MySpine Pedicle Screw Placement Guides was conducted in accordance with various international standards and FDA guidance documents.

Non-clinical testing included biocompatibility testing to ISO 10993 applicable to external communicating devices with limited (<=24 hrs) contact duration, dimensional accuracy and precision before and after sterilization, mechanical testing, cleanliness following factory cleaning, and a shipping test of the packaged device. Process reproducibility was assessed. The software tools used to manufacture the MySpine Pedicle Screw Placement Guides were validated for their intended use.

MySpine Pedicle Screw Placement Guides were tested as part of design verification to written protocols with pre-defined acceptance criteria. The testing was conducted on the worst case component size and option/design. The testing met all acceptance criteria and verifies that the performances of the MySpine Pedicle Screw Placement Guides are substantially equivalent to the predicate devices. Design validation was accomplished with a cadaver laboratory.

Conclusion

Based on the above information, the MySpine Pedicle Screw Placement Guides can be considered as substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 23, 2014

Medacta International SA
% Mr. Adam Gross
Medacta USA
4725 Calle Quetzal, Unit B
Camarillo, California 93012

Re: K132788
Trade/Device Name: MySpine Pedicle Screw Placement Guides
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI
Dated: April 29, 2014
Received: April 30, 2014

Dear Mr. Gross:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K132788

Device Name
MySpine Pedicle Screw Placement Guides

Indications for Use *(Describe)*
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MySpine Screw Placement Guides are intended for single use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

James P. Bertram -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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